

Predicting Outcomes of Intermediate Term Complications and Revisional Surgery Following Laparoscopic Adjustable Gastric Banding: Utility of the CORE Classification and Melbourne Motility Criteria

Paul Robert Burton · Wendy A. Brown ·
Cheryl Laurie · Geoff Hebbard · Paul E. O'Brien

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Abstract

Background Patients with laparoscopic adjustable gastric bands (LAGB) present at times with adverse symptoms or unsatisfactory weight loss, where a liquid contrast swallow or upper gastrointestinal endoscopy is not diagnostic. Stress barium and high resolution manometry are promising investigations, however, have not yet been established as clinically useful.

Methods Patients with an unsatisfactory outcome following LAGB, where liquid contrast swallow and endoscopy were not diagnostic, were evaluated using high resolution video manometry and a stress barium. Pre-operative and follow-up clinical data were collected. Esophageal motility was assessed using the Melbourne criteria.

Results There were 143 participants in the study. Stress barium identified the following appearances: gastric enlargement ($n=57$), transhiatal enlargement ($n=44$), pan-esophageal dilatation ($n=9$), and anatomically normal ($n=33$). Twenty-four (72%) of the anatomically normal patients had deficient esophageal motility. Revisional LAGB surgery was performed in 56 patients. This was successful in gastric

enlargements when motility was intact (percentage of excess weight loss (%EWL) 58.3 ± 16.2 vs. 35.4 ± 19.7 , $p=0.002$). Revisional surgery for transhiatal enlargements improved symptoms but did not improve poor weight loss (%EWL 20.6 ± 24.9 vs. 17.2 ± 25 , $p=0.1$).

Conclusions The CORE classification combines anatomical change with esophageal motility and has been defined for intermediate term complications following LAGB where conventional investigations have not been diagnostic. Revisional LAGB surgery is helpful for patients with a gastric enlargement above the LAGB if esophageal motility is intact. If motility is deficient or there is an esophageal anatomical abnormality, intervention is not likely to remedy poor weight loss.

Keywords CORE classification · Melbourne criteria · Laparoscopic adjustable gastric band · Complications · Outcomes · Obesity · Stress barium · High resolution manometry · Esophageal motility · Video manometry

Introduction

The laparoscopic adjustable gastric band is well established as a safe, effective, and durable bariatric procedure [1]. Modification of the original surgical technique has largely overcome the problem of early gastric prolapse [2]. Data, out to 8 and 12 years, with high follow-up rates have demonstrated maintenance of weight loss [3, 4].

Others, however, have reported higher complication and failure rates in the intermediate term [5, 6]. Differences in reported outcomes are possibly accounted for by differing definitions and management of postoperative complica-

P. R. Burton (✉) · W. A. Brown · C. Laurie · P. E. O'Brien
Centre for Obesity Research and Education (CORE),
Monash University, The Alfred Hospital,
Commercial Rd Prahran 3181,
Melbourne, Australia
e-mail: paul.burton@med.monash.edu.au

G. Hebbard
Department of Gastroenterology and University of Melbourne,
Royal Melbourne Hospital,
Parkville,
Melbourne, Australia

tions. Controversy in this area is not surprising as the complex spectrum of pathophysiology that can occur after LAGB has, until recently, been poorly defined [7]. With ongoing use and an estimated 500,000 LAGB placed worldwide, sensitive diagnostic tests able to objectively stratify treatment are urgently required. Robust definitions of complications are also required to facilitate comparative outcome studies.

The two most common intermediate term complications in the pars flaccid era are acute luminal dilatations above the LAGB or chronic symmetrical dilatation of the gastric pouch [7]. Acute dilatation is usually well managed with the removal of saline from the LAGB and attention to eating behavior [8, 9]. A regular, ongoing follow-up program should identify these problems and facilitate intervention at an early stage, although, if left untreated, a more significant problem may evolve [10].

Symmetrical gastric pouch dilatation, where there is focal luminal dilatation above the LAGB, is now the most common indication for revisional LAGB surgery, which is generally a successful strategy [11, 12]. There are, however, a group of patients who present with significant adverse symptoms or increasing weight despite a normal or equivocal liquid contrast swallow or endoscopy. Alternatively, revisional LAGB surgery may resolve an anatomical problem; however, it fails to correct the clinical situation, suggestive of a functional problem.

Use of a semi-solid stress barium and high resolution manometry has shown that patients with no clear explanation for unsatisfactory progress frequently have inducible anatomical abnormalities above the LAGB or specific patterns of esophageal dysmotility [7, 13]. These new data have provided insights into the pathophysiology associated with LAGB; however, they have not yet been translated to clinical use.

We hypothesized that gastric dilatations would be amenable to surgical correction, providing that the critical aspects of esophageal motility remained intact. Esophageal dilatation, focal or pan-esophageal, or deficient motility was not expected to be amenable to surgery or improve substantially with conservative management. We aimed to integrate recently described criteria for assessing esophageal motility with patterns of anatomical change induced with a stress barium. By doing this we aimed to develop a clinically useful classification of complications following LAGB, predictive of the response to different treatment strategies.

Methods

The Melbourne Health, Monash University, and Avenue Hospital human ethics committees approved this research,

and all patients gave informed consent. A prospective observational study was conducted on consecutive LAGB patients who presented with unsatisfactory progress.

Subjects

Patients with unsatisfactory progress following LAGB, for the purposes of this study, were defined as those aged between 18 and 65 years who experienced either poor weight loss (<25% of excess weight loss 12 months postoperatively) and/or had adverse symptoms (volume reflux, dysphagia, regurgitation/vomiting, or the inability to tolerate fluid in the LAGB due to these symptoms) despite a normal or near normal liquid contrast swallow or upper gastrointestinal endoscopy. Confirmation that the patient had attended regular follow-up over at least 3 months, with attempts to optimize the LAGB adjustment, was also required. Therefore, this study was of a select group of patients in whom there was no obvious anatomical abnormality and routine management had proven unsuccessful.

Pre-operative Clinical Assessment

Prior to video manometry, each patient completed a standardized questionnaire that constituted validated reflux (0 no reflux, 72 severe reflux) and dysphagia (0 no dysphagia to 45 total dysphagia to water) scores [14, 15]. A standardized clinical interview was conducted prior to the study. The most significant or primary presenting symptom was categorized as one of reflux, dysphagia, or loss of satiety.

Video Manometry

All patients underwent a standardized high resolution video manometry study, incorporating a semi-solid stress barium. Video manometry was performed as has been previously described [16]. In brief, a water perfused manometry system with a custom-made 21-channel silicone rubber manometry catheter (Dentsleeve, Ontario, Canada) was used. The catheters were designed specifically to assess the region of the esophago-gastric junction and to differentiate the pressure signals generated by the LAGB and lower esophageal sphincter. The manometry system was connected to a personal computer via data acquisition and video input cards (National Instruments, Austin, TX). Simultaneous high resolution manometry and video fluoroscopy information was recorded using TRACE! 1.2 (written by G Hebbard using LabVIEW, National Instruments, Austin, TX).

Supine basal recording was performed for 30 s without swallowing. Ten wet swallows of 5 ml of water were then performed with the patient in the right lateral position.

Analysis of Esophageal Motility

Esophageal motility was assessed using adapted criteria specific to LAGB patients, defined as the Melbourne criteria [13]. This was a modified version of the Chicago criteria, the current standard for reporting high resolution manometry [17]. Detailed analysis of the lower esophageal contractile segment was undertaken to make these specific to LAGB patients [13, 17]. For the purposes of analysis, esophageal motility was classified as intact or deficient. Intact motility included patients who had normal or mild impairment in peristalsis whereas a severe peristaltic impairment constituted deficient motility.

Stress Barium Protocol

Patients ingested two consecutive spoonfuls of barium-soaked porridge. These were followed immediately by drinking of up to 80 ml of liquid barium via a straw. Patients were instructed to continue drinking until either symptoms of dysphagia, discomfort, or nausea developed or they felt excessively full. The aim was to maximally distend the lumen above the LAGB. Fluoroscopy was used to ensure patients had drunk barium to the point of either developing reflux from the pouch or a significant enlargement (with stasis) was observed above the LAGB. We aimed to generate an intraluminal pressure immediately above the LAGB of at least 30 mmHg. Delayed images were taken intermittently for a period of up to 5 min, to document transit and emptying of the lumen above the LAGB.

Analysis of Stress Barium

The anatomical appearance observed at stress barium was central to the analysis of data, with patients primarily categorized on this appearance. An enlargement was defined as a focal or generalized luminal dilatation above the LAGB in which there was stasis. The appearance was classified as gastric enlargement (either symmetrical gastric dilatation or gastric prolapse), transhiatal enlargement, generalized (pan) esophageal dilatation, or anatomically normal.

Management following Video Manometry

The pathophysiological change was documented as was motility, and a report was provided. Post manometry management was at the discretion of the referring clinician.

Revisional surgery was performed using a standard technique where the old LAGB was removed and the crural pillars mobilized and repaired anteriorly. A new posterior pathway for the LAGB was created with a broad

anterior gastro-gastric fixation. A liquid contrast swallow was performed postoperatively to confirm accurate placement of the LAGB.

Patient Follow-up

All patients were followed up for a minimum of 6 months following video manometry. Weight loss data were recorded 6 months following video manometry if operative intervention had not occurred and was not planned. If a re-operation was performed, weight loss data were recorded 6 months following this. All patients who underwent re-operation were contacted by phone, and a matched follow-up questionnaire was completed.

Statistical Analysis and Data Management

All statistical analysis was performed using SPSS V. 16.0 (SPSS Inc., Chicago, IL). Data are displayed as mean and standard deviation if normally distributed or median and interquartile range if not normally distributed. Paired *t* tests were used for analysis of repeat measurements of normally distributed continuous data. Student's *t* tests were used for comparisons of normally distributed continuous independent data. Mann–Whitney tests were used for analysis of non-normally distributed continuous data. One-way ANOVA was used for comparison of multiple normally distributed continuous variables. Kruskal–Wallis tests were used for comparison of multiple non-normally distributed continuous variables. A two-sided *p* value of 0.05 was considered statistically significant.

All weight loss and demographic data were sourced from a prospectively maintained online database (www.lapbase.net).

Results

Data from 143 patients were available for analysis. Patient details are shown in Table 1, based on the anatomical appearance at stress barium. Significant baseline differences existed between the groups in terms of percentage of excess weight loss (%EWL) at follow-up, %EWL at presentation, and peak %EWL. Peak %EWL was the maximal weight loss the patient had achieved following LAGB. Notably, the mean peak weight loss was over 50% EWL.

The gastric enlargements included three gastric prolapses that were not seen on liquid contrast swallow, although were induced by the addition of saline to the LAGB and the stress barium. The method for differentiating transhiatal esophageal from gastric enlargements herniating through the hiatus has previously been described [7].

Table 1 Patient details (*n*=143)

	Transhiatal esophageal enlargement	Gastric enlargement	Anatomically normal	Pan-esophageal dilatation	<i>p</i> value
Number	44 (31%)	57 (40%)	33 (23%)	9 (6%)	–
Age (years)	48±9.3	45.7±13.2	46.5±9.4	50.2±7.4	0.45
%EWL at presentation	26.3±3.6	52.8±30.2	24.1±21.8	46.1±15.0	<0.005
Peak %EWL	56.5±25.4	68.3±26.8	51.1±24.3	67.4±9.1	0.03
%EWL at follow-up	24.1±23.1	49.6±26.4	22.4±23.4	41.1±19.5	<0.005
Start BMI (kg/m ²)	43.5±7.3	44.5±7.7	44.2±7.9	48.6±7.0	0.61
Start weight (kg)	120.0±23.3	121.6±22.9	120.3±21.3	148.2±26.2	0.10
Duration from initial surgery (days)	1,655±950	1,545±784	1,893±933	2,367±976	0.20
Revision LAGB since manometry	14 (32%)	34 (61%)	8 (24%)	0	0.005

Symptoms at Presentation

The gastric enlargement group most commonly identified reflux as the primary symptom. The pan-esophageal dilatation patients all presented primarily with loss of satiety. The transhiatal enlargement group presented equally with reflux and dysphagia, whereas the anatomically normal group presented more commonly with dysphagia. These differences between the primary presenting symptoms in the groups were significant (*p*<0.005). Figure 1 summarizes these data.

Esophageal Motility

Using conventional (Chicago) criteria for the assessment of esophageal motility, there was no difference, between groups, in the proportion of patients with intact motility

(*p*=0.43). The Melbourne criteria demonstrated statistically significant changes in the proportion classified as having intact motility within each group (*p*<0.05) compared to use of the Chicago criteria. These data are shown in Fig. 2. Application of the Melbourne criteria showed that motility was significantly better in the gastric enlargement group compared to the anatomically normal and transhiatal groups (*p*=0.02). The pan-esophageal dilatation group was excluded from motility analysis, as they had no peristaltic function. Within the anatomically normal group, 24 (72%) patients had a significant abnormality of esophageal peristalsis. This allowed the division of this group into those with severe peristaltic impairment (deficient motility) and a functional group, with no anatomical or physiological explanation for the symptoms or outcome.

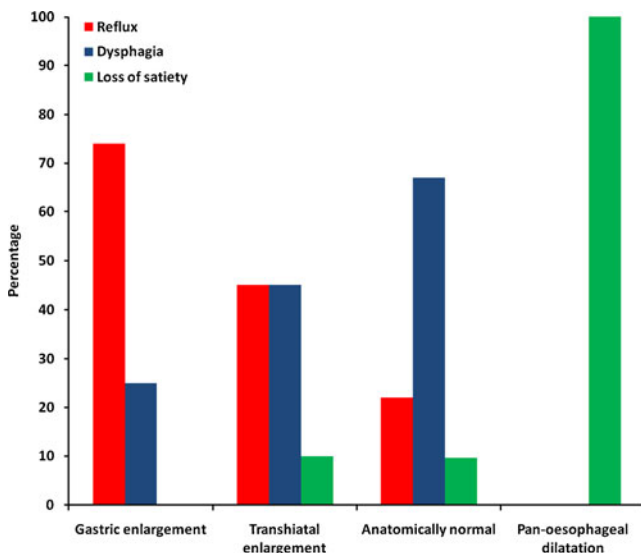


Fig. 1 Primary presenting symptom

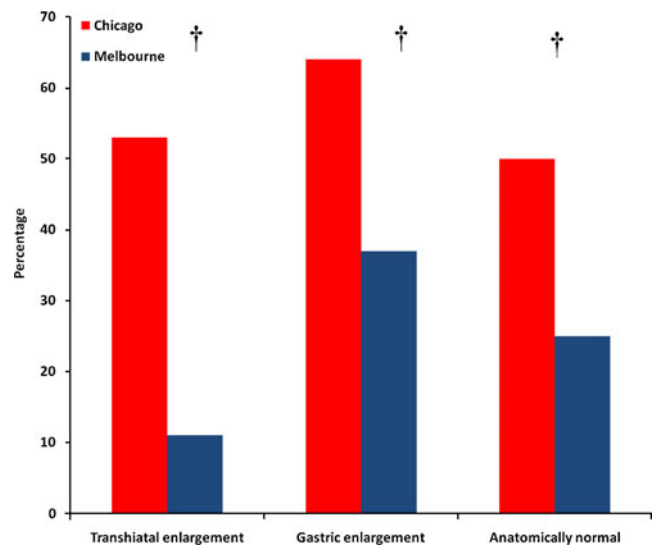


Fig. 2 Percentage of patients with intact esophageal motility using specific (Melbourne) vs. conventional (Chicago) high resolution manometry criteria. †*p*<0.05

Management and Outcome

Fifty-six patients underwent revisional LAGB surgery following video manometry. More patients with gastric enlargements underwent revisional LAGB surgery (Table 1), compared to patients with transhiatal enlargements or no anatomical abnormality. Revisional LAGB surgery had no effect on excess weight loss in any group. In the gastric enlargement group, mean %EWL was 52.8 ± 30.2 at presentation for video manometry, and this was maintained at follow-up postoperatively. In the transhiatal and anatomically normal groups, mean %EWL was <25 at presentation and did not improve following revisional surgery.

Figure 3 summarizes these data. Reflux and dysphagia scores improved significantly in both the transhiatal ($p < 0.005$, $p < 0.007$) and gastric enlargement groups ($p \leq 0.005$, $p < 0.007$) but were unchanged in the anatomically normal group ($p = 0.16$, $p = 0.19$). These data are summarized in Fig. 4.

Revisional Surgery for Gastric Enlargements

Patients with gastric enlargements who had intact esophageal motility maintained good weight loss following revisional surgery. Patients with deficient esophageal motility were found to have increased their weight at follow-up, such that the difference between the two groups was statistically significant ($p = 0.002$). Data are shown in Table 2.

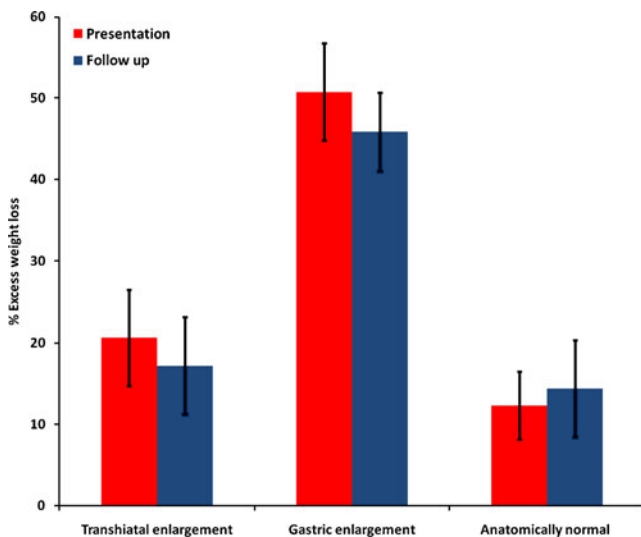


Fig. 3 Weight loss following revisional LAGB surgery. There was no statistically significant change in %EWL following revisional surgery in any group. Data are mean and standard error

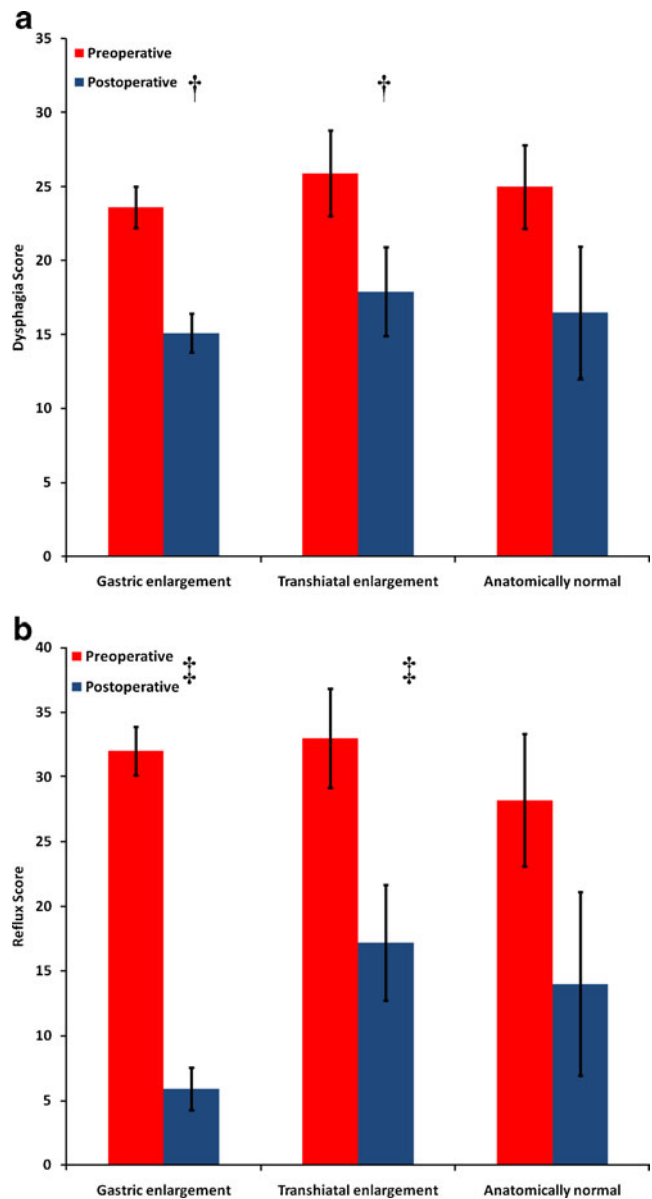


Fig. 4 Change in dysphagia and reflux symptoms following revisional LAGB surgery: **a** dysphagia score **b** reflux score. Data are mean and standard error. † $p < 0.05$, ‡ $p < 0.05$

The CORE Classification

As a result of these collective data, we defined the CORE classification of intermediate term complications following LAGB. This classification combined anatomical appearance with an assessment of esophageal motility. Three general anatomical appearances at stress barium were identified:

1. Gastric enlargements
2. Esophageal enlargements
3. Anatomically normal

Table 2 Outcomes of revisional surgery in patients with gastric enlargements

	Intact motility (n=13)	Deficient motility (n=21)	p value
Age (years)	42±11	43±9	0.82
Pre-operative reflux score (0–72) ^a	35.3±11.7	31.1±10.5	0.30
Pre-operative dysphagia score (0–45) ^b	21.4±8.3	23.7±7.7	0.43
Postoperative reflux score (0–72) ^a	2.5±2.5	8.6±11.6	0.05
Postoperative dysphagia score (0–45) ^b	14.0±4.9	15.2±8.5	0.66
Excess weight loss at follow-up (%)	58.3±16.2	35.4±19.7	0.002
Excess weight loss at manometry (%)	59.9±30.1	44.1±30.1	0.18

^a0 is no reflux, 72 severe reflux

^b0 is no dysphagia, 45 total dysphagia to liquids

The nature of the anatomical appearance can be made more specific within each category, and these data supplemented with high resolution manometric data. Table 3 summarizes the key features of each category. Figure 5 illustrates the anatomical abnormalities.

Discussion

We evaluated the outcomes of LAGB patients where no explanation for unsatisfactory progress had been identified with a liquid contrast swallow or upper gastrointestinal endoscopy. Use of a stress barium contrast swallow allowed the anatomy above the LAGB to be determined; illustrating various luminal enlargements. Application of the Melbourne criteria, high resolution manometry criteria adapted to LAGB patients, made the assessment of esophageal motility highly clinically relevant. Combining the anatomical appearance with assessment of specific aspects of

esophageal motility allowed the CORE classification of intermediate term complications following LAGB to be defined. This classification was found to be clinically relevant, able to guide treatment.

Our data show that patients with gastric enlargements above the LAGB respond well to revisional LAGB surgery, provided esophageal motility is intact. Other problems associated with esophageal dilatation or deficient esophageal motility generally present with poor weight loss and are not responsive to further LAGB treatment.

We emphasize that this was a study of a specific patient group, representative of only a small proportion of the total post LAGB population. Only those patients where conventional investigations and treatment had been unhelpful were included. These patients, however, are a major challenge in optimizing the intermediate term outcomes after LAGB surgery. Significantly, the majority of these patients had achieved a good weight loss initially with a mean EWL of >50% in each group.

Table 3 Key features of the CORE classification: based on appearance at stress barium

Abnormality	Proportion ^a	Key features
Gastric enlargements (40%)		
Symmetrical sub-diaphragmatic	34%	Symmetrical enlargement of stomach arising below the diaphragm, although may impinge on the hiatus as it expands. Patients frequently present with significant reflux symptoms. Intact motility predicts a good outcome following revisional LAGB surgery
Transhiatal	2%	True hiatus hernia, with excess stomach above the LAGB transiting up into the thoracic cavity
Prolapse	4%	Prolapse can be considered a (asymmetrical) gastric enlargement; can be anterior or posterior
Esophageal enlargements (37%)		
Transhiatal	31%	Focal esophageal enlargement, transiting the hiatus; have mixed symptoms of dysphagia and reflux; esophageal motility is frequently significantly impaired.
Pan-esophageal	6%	Pan-esophageal dilatation, with a normally placed LAGB; the esophagus demonstrates no ordered peristaltic contractions; patients do not have satiety but may also report reflux or regurgitation
Anatomically normal (23%)		
Deficient motility	17%	Severe impairment in esophageal motility with anatomically normal stress barium; the impairment in motility is often only identified at high resolution manometry using the Melbourne criteria, specifically a significant impairment in the lower esophageal contractile segment. Dysphagia symptoms are common
Intact motility	6%	Anatomically normal stress barium with intact esophageal motility including lower esophageal contractile segment. No specific cause for unsatisfactory progress identified

^a Proportions are of number of patients included in this series

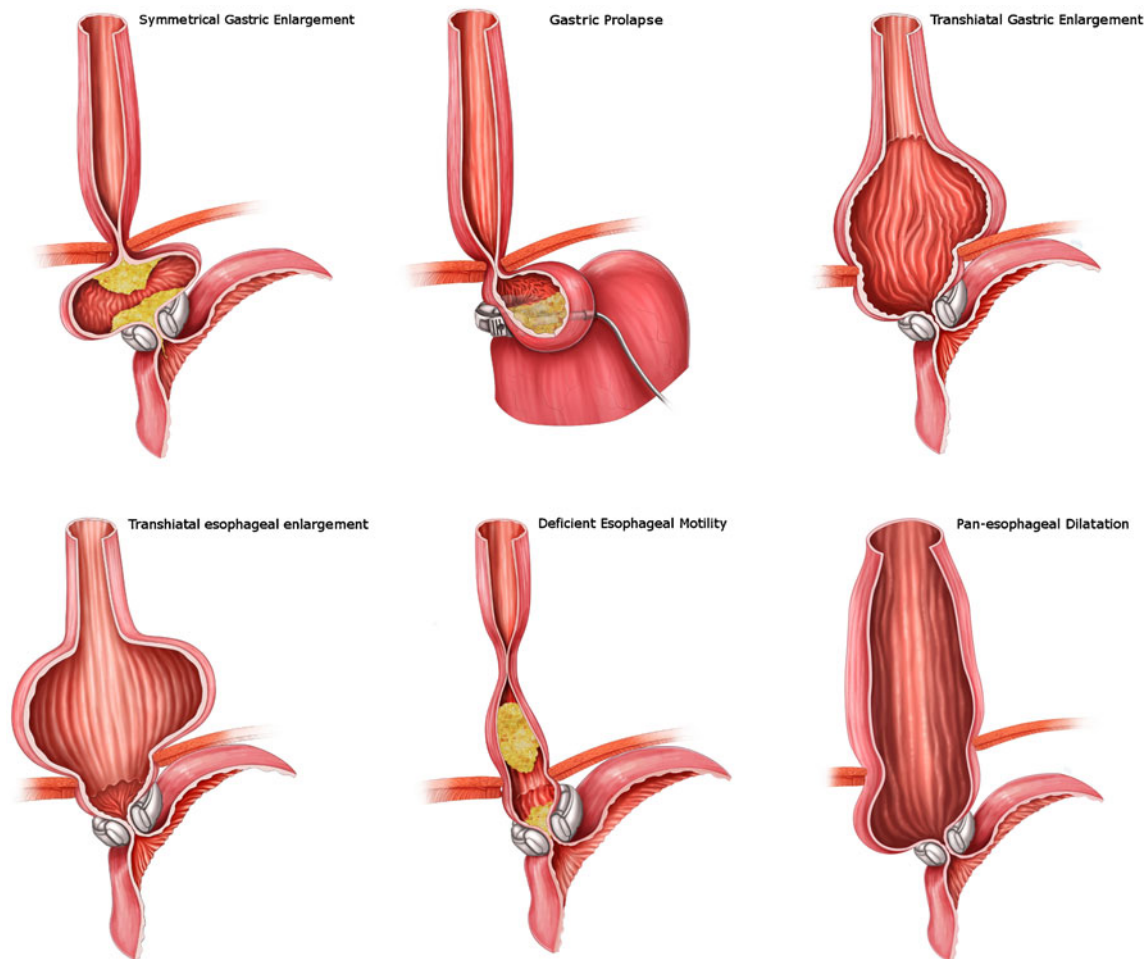


Fig. 5 Schematic representation of the CORE classification. Typical patterns represented by the CORE classification are schematically demonstrated. To determine optimal treatment, it is critical to

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If initial investigations are not diagnostic or conventional treatment unsuccessful, more detailed assessment with a stress barium and/or high resolution manometry has now been shown to be useful in managing these patients.

Patients with different anatomical or motility problems presented with different symptoms. Although symptoms were not always specific, gastric enlargements were primarily associated with reflux. Patients with transhiatal esophageal enlargements had a range of symptoms. Alternatively, patients with no anatomical abnormality tended to present with dysphagia, likely reflective of impaired bolus transit. Pan-esophageal dilatation was always primarily associated with the loss of satiety, suggestive of a loss of visceral sensitivity.

Initial adjustments to LAGB volume or revisional surgery to correct a mechanical problem such as prolapse or symmetrical gastric pouch dilatation resolve most post LAGB problems [8, 11]. Our data now support this approach in cases where the gastric enlargement is more subtle, being identified only by a stress barium. We have

also extended knowledge by showing that regardless of anatomy, intact motility is important in mediating a successful outcome after revisional surgery.

Re-operating on patients with transhiatal enlargements appeared to improve symptoms; however, it did not impact on unacceptable weight loss (25% EWL). We therefore cannot see that revisional LAGB surgery is worthwhile in this situation.

Transmission of excess force to the luminal wall is suspected of underpinning luminal dilatations and impairments in the contractile function of the lower esophageal sphincter. Possibly, these problems represent aspects of the same spectrum of pathophysiology, with anatomical change occurring at a later stage. During normal swallows, transmission of force to the luminal wall has been shown to be mediated by how tight the LAGB is when measured as an intraluminal pressure [18]. Also, episodes of acute obstruction result in very elevated intraluminal pressures and are mediated by the amplitude of proximal esophageal peristalsis [18].

To avoid the transmission of force to the luminal wall, adjusting the LAGB to target satiety not mechanical restriction is advocated. Good eating behavior is emphasized, ensuring that portion sizes are small. Each mouthful must be chewed well before being swallowed. If the LAGB is inducing adverse symptoms, we should seek to relieve any obstruction by removing saline promptly.

The question of how best to manage patients with an established problem that is not amenable to further LAGB treatment remains difficult. There is much discussion among surgeons about converting one bariatric procedure to another. An advantage of LAGB is its ease of reversibility. Therefore, if desired, an alternate bariatric procedure can be performed. Several studies have shown that different bariatric procedures can be converted to an alternate procedure [19, 20]. High quality prospective studies will be needed to definitively answer these questions.

If conversion to an alternate procedure is undertaken, we suggest that the LAGB be removed several months prior to sleeve gastrectomy or gastric bypass to make the procedure technically easier and reduce the risk of anastomotic leak. Alternatively, a biliopancreatic diversion avoids the proximal stomach and should not be affected by a previous LAGB.

A limitation of this study was its observational nature. We did not randomize treatment arms. Therefore, definitive conclusions about treatment need to be treated with some caution. Our data, however, strongly proffered messages that we are comfortable in adopting in our practice. In the future, this classification facilitates prospective, objective evaluations of different treatments or preferably preventative strategies.

Unsatisfactory progress in LAGB patients with either adverse symptoms or poor weight loss can usually be explained by pathophysiology or anatomical change. A stress barium and high resolution manometry are now sensitive, validated diagnostic tests. This facilitates selection of treatment with an accurate means of predicting outcome. The future challenge is to develop strategies that prevent these problems from developing as well as better understanding how and why they occur.

Declaration

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